K063313

DEC - 5 2006

510(k) Summary

(This Summary is submitted in accordance with 21 CFR Part 807, Section 807.92)

Submitter's Name:	Boston Scientific Corporation
Submitter's Address:	2011 Stierlin Court Mountain View, CA 94043-4655
Contact Person:	Donna Page Manager, Regulatory Affairs, Carotid Programs (650) 623-1708 (650) 623-1790 FAX paged1@bsci.com
Device Proprietary Name:	FilterWire EZ™ Embolic Protection System (3.5 mm – 5.5 mm)
Device Common Name:	Embolic Protection Device
Device Classification Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code NTE)
Device Class:	Class II
Date Prepared:	November 30, 2006

Identification of Predicate Device:

The Boston Scientific FilterWire EZ™ Embolic Protection System (FilterWire EZ System) is substantially equivalent in design and intended use (embolic protection) to the same devices legally marketed under K032884 (3.5 mm to 5.5 mm) and K061332 (2.25 mm to 3.5 mm) for use in saphenous vein bypass grafts. The FilterWire EZ System is also substantially equivalent in design and indications for use to the RX ACCUNET™ Embolic Protection System (K042218) legally marketed as an embolic protection device for use in the carotid vasculature.

Device Description:

The Boston Scientific FilterWire EZ System (3.5 mm – 5.5 mm) is a temporary intra-vascular 0.014" guide wire filtration system that is placed distal to the vessel lesion to be treated by interventional procedures. The system consists of a Protection Wire, an EZ Delivery Sheath, an EZ Soft Tip Retrieval Sheath and accessories. A separately packaged EZ Bent Tip Retrieval Sheath is also available as an alternate tool for retrieving the FilterWire EZ Protection Wire. The 190 cm wire is compatible

with the Boston Scientific extension wire (K970376 cleared June 6, 1997) for over-the-wire catheter exchanges.

The FilterWire EZ System is delivered via the EZ Delivery Sheath. Once the Protection Wire is across the lesion, the filter bag is expanded in the artery lumen by removing the EZ Delivery Sheath. After treating the lesion, all interventional devices are removed, and the EZ Soft Tip Retrieval Sheath or EZ Bent Tip Retrieval Sheath is advanced to the proximal end of the filter and the filter loop is retracted into the EZ Retrieval Sheath, trapping any emboli caught during the procedure. The EZ Retrieval Sheath and Protection Wire are then removed from the patient simultaneously.

Indications for Use:

The FilterWire EZ™ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts and carotid arteries. The diameter of the vessel at the site of filter loop placement should be between 2.25 mm and 5.5 mm for coronary saphenous vein bypass graft procedures and between 3.5 mm and 5.5 mm for carotid procedures.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature, peripheral vessels other than carotid arteries, or in treating native coronaries, including acute myocardial infarction.

Summary of Technological Characteristics:

The FilterWire EZ System (3.5 mm to 5.5 mm) indicated for use in the carotid vasculature is the same device indicated for use in saphenous vein bypass grafts. The design, principles of operation and materials are identical to the predicate FilterWire EZ System cleared under K032884. The FilterWire EZ System is also equivalent in design and indications to the RX ACCUNET Embolic Protection System cleared under K042218. The following design attributes are the same or similar for the subject device and the identified predicate devices:

- Rapid Exchange (RX) delivery systems
- Filter based technology
- Nitinol® filter/basket component
- Polyurethane filter membrane
- Compatibility with .014" guide wires
- Compatibility with 6F guide catheters
- Available in 190 and/or 300 cm lengths
- Accommodates similar vessel sizes
- Radiopaque guide wire tips and/or delivery sheath tips
- Radiopaque markers on filter loop

Performance Data:

FilterWire EZ System in-vitro testing consisted of dimensional testing, tensile/torque testing and functional testing. Biocompatibility, packaging testing, product shelf life testing and functional testing in animal models have also been successfully conducted. Test results verified that the FilterWire EZ System met all applicable product specifications for its intended use.

The clinical performance of the FilterWire EZ System (3.5 mm – 5.5 mm) was evaluated in conjunction with the NexStent™ Carotid Stent (NexStent) in a carotid artery stenting clinical trial (CABERNET) sponsored by EndoTex™ Interventional Systems, Inc. The results of the CABERNET Trial were used in support of the NexStent PMA, P050025.

Results of the CABERNET Trial are presented in the FilterWire EZ System Directions for Use (DFU).

Statement of Substantial Equivalence:

Boston Scientific Corporation considers the FilterWire EZ System substantially equivalent to the FilterWire EZ System legally marketed by Boston Scientific Corporation and to the Guidant RX ACCUNET Embolic Protection System based on a comparison of intended use and the results of in-vitro testing, in-vivo testing, and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2006

Boston Scientific Corporation
c/o Ms. Donna Page
Manager, Regulatory Affairs, Carotid Programs
2011 Stierlin Court
Mountain View, CA 94043-4655

Re: K063313
Boston Scientific FilterWire EZ™ Embolic Protection System (3.5 mm – 5.5 mm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: November 1, 2006
Received: November 2, 2006

Dear Ms. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Holmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K063313

Device Name: FilterWire EZ™ Embolic Protection System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

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